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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,217	12/12/2001	Thomas Raschke	Beiersdorf 754-KGB	8909

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,217

Applicant(s)

RASCHKE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 10-20 are pending. The Amendment filed 6/23/04, amended claim 10.

The 35 USC 112 rejection in the previous Office Action is hereby withdrawn. In the response filed 6/23/04, Applicant directed the Examiner to page 9, 3rd paragraph, for support for the active ingredient comprising (a) and (b). The third paragraph of page 9 of the instant specification clearly supports this limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/37282. See US 6,503,518, which is an English language equivalent, as verified by a USPTO translator, of WO 99/37282, for citation purposes.

The instant invention is directed toward a composition comprising an aqueous phase, a lipid phase, and an active ingredient consisting of a combination of one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid and alpha-lipoic acid. The instant invention is further directed to applying such a composition to the skin.

US 581 is directed to cosmetic and dermatological compositions that comprise one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid (abstract). US '518 discloses at column 4, lines 51-53 that the compositions

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preferably contain antioxidants. Lipoic acid is disclosed as a suitable antioxidant at column 4, lines 58-65. For glyceryl stearate citrate as a partially neutralized ester of monoglycerides and/or diglycerides of saturated fatty acids with citric acid within the instant claimed concentration ranges and oil-in-water emulsions see the examples beginning at column 8. See also claims 1 and 2. For lotions and creams see col. 6, lines 34-41. For gels see col. 10, line 54. Antioxidants (lipoic acid) are taught as comprising 0.001-30% of the composition and glyceryl stearate citrate (part (a) of the instant claims) is exemplified as comprising 3% of the composition. Thus the ranges of “(b)/(a)” of the instant claims are met by the teachings of US ‘581.

US ‘518 does not explicitly teach one composition comprising both one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid and alpha-lipoic acid or application to the skin. However, US ‘518 teaches compositions comprising one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid and antioxidants, wherein lipoic acid is taught as an antioxidant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify a composition comprising one or more partially neutralized esters of monoglycerides and/or diglycerides of saturated fatty acids with citric acid and alpha-lipoic acid because of the expectation of achieving a composition that is particularly advantageous (see Col. 4, lines 51-57) and because of the expectation of achieving enhanced stability.

US ‘518 does disclose that lipoic acid can be added to the composition for its antioxidant properties. Nothing unobvious is seen in substituting the known claimed isomer for the compound of US ‘518 since such structurally related compounds suggest one another and would

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be expected to share common properties absent a showing of unexpected results. It is well-known and common practice to apply cosmetic and dermatological compositions to the skin. Therefore, application of the composition to the skin as instantly claimed is not considered patentable over the prior art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of US '518 using any isomer of lipoic acid and apply it to the skin expecting to obtain a cosmetic and dermatological composition with antioxidant properties.

It is respectfully pointed out that US '518 teaches a composition comprising (a), an aqueous phase, and a lipid phase. The reference additionally teaches that antioxidants, such as lipoic acid (component (b) of the instant invention), can be added to the composition. Thus, US '518 teaches a composition comprising an aqueous phase, a lipid phase, and an active ingredient, wherein the active ingredient consists of (a) and (b).

The Examiner respectfully points out that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the phrases "providing improved stability of its chemical constituents" and "that imparts the improved stability to the composition" in instant, independent claim 10 is not afforded patentable weight.

Response to Arguments

Applicant argues, "Although the '518 discloses antioxidants, there is not disclosure of the use of antioxidants to stabilize the constituents of the compositions. The '518 deals mainly with formulating low-viscosity compositions and does not disclose any synergistic or unexpectedly superior results that would result from employing alpha-lipoic acid as the sole component of (b)". This argument is not persuasive. First, this argument is not commensurate in scope with the instant claims. The instant claims are not directed toward synergism or unexpected results, and the instant claims are product claims, not method of use claims. As pointed out in the above rejection, the intended use of a composition is not given patentable weight.

Regarding Applicant's arguments toward unexpected results (i.e., synergism/unexpected results), the Examiner respectfully directs Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). It is respectfully pointed out that Applicant has not met their burden in providing unexpected results.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

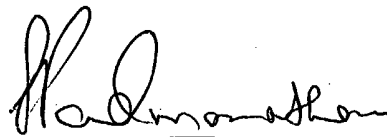
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**